

Description of caBIG Data Standards Governance (Draft 10/18/2004)

Following is a description of a proposed process for governance of a standardization process of common data elements (CDEs) used in caBIG. The process is described graphically in Exhibit 1, caBIG CDE Harmonization Process that depicts the proposed CDE harmonization process from the proposal of harmonization candidates through the development of well-formed CDEs to periodic review and maintenance of the preferred CDEs. This process will be institutionalized through the cooperation of all participating Contexts and Workspaces. It builds upon successful processes in place in individual NCI contexts and is designed to enhance those, not replace them. The described process is one that will be ongoing, with CDEs being proposed for standardization in an iterative fashion.

Identify Qualified CDEs

Proposing CDEs for caBIG standards. Data elements can be proposed for standardization through two different paths. One, Contexts, Workspaces or the caBIG V-CDE Workgroup can propose individual existing data elements for potential standardization. Two, a Subject Area Team (for example, stakeholders and contractor staff, or a Workspace Special Interest Group) can select existing or create new data elements to be included in a subject area standardization proposal.

Review and Recommendation of Existing CDEs. A Context, Workspace, or V-CDE can review existing CDEs as potential standards. Potential standard CDEs will then be reviewed for data quality and metadata completeness. Once a CDE achieves a certain level of completeness and approval, a group can set a workflow status to indicate that it can be shared (or designated by another group). This will trigger a review for conferring the Qualified registration status on the element, putting it into the pool for further consideration for standardization. Data elements with the Qualified registration status must be fully described, according to the ISO/IEC 11179 standard, and have been reviewed and approved by a group of subject matter experts at some level. The originating group should review the caDSR for similar CDEs to the one being proposed for standardization and try to identify if the CDE might already be part of a relevant external standard. Retiring any duplicate data elements or harmonizing with other CDEs and/or external standards during this review process will improve the CDE collection.

Nominations from a Subject Area Review. The Subject Area Team can initiate a review of data elements that are related to a certain concept or business area. This would involve creation of a list of the data elements and associated attributes related to a particular business topic. The list would contain suggestions for data element names and definitions, permissible values (value domains), and sample questions that could be used on an information collection form. Following are the steps in the review process that will be used to develop a set of CDEs:

- A Subject Area Team would search the caDSR for CDEs that are well formed, of the appropriate workflow status, and reusable across contexts. Generally, data elements

reviewed will be those with at least the Qualified registration status, but some additional elements may be considered including those with no registration status or those from relevant external standards.

- The CDEs would be compared with data elements from external standards. The Team would review related data standards from external sources for adoption in the caDSR.
- A draft CDE list would be developed based upon the review. This list would include related data elements from the caDSR, as well as those from other sources such as external standards, if relevant.
- The Team would review the initial list and provide comments via a feedback mechanism for receiving and disseminating comments. They would discuss how to handle duplicates, and which data element met the needs across contexts.
- Potential standard CDEs would be added, modified, or removed from the list based on reviewers' comments. Multiple iterations of review may be necessary to ensure that the CDEs meet the needs of all interested contexts. If CDE attributes need to be modified to meet broader needs, a new CDE would be created and assigned to a context, such as the caBIG context.

Reuse of CDEs by Designation. Any data element that is considered to be useful to more than one context is a potential standard CDE. Data elements that are designated by more than one context can be considered as part of a pool to be reviewed for potential standardization. An initial effort by Context Administrators to review data elements in other contexts and designate them for use in their own contexts will also create a pool of candidate standard CDEs.

Promote as Candidate Standards

Assignment of Candidate Registration Status. A Candidate registration status will be assigned if a data element is designated by multiple contexts, or if it is part of a group of elements that have been reviewed for standardization, and have successfully completed a review for quality and completeness. A developing organization can decide not to progress a candidate standard or to do further modification/clarification before reconsidering the potential standard.

Review and Comment Period. After the assignment of Candidate Status, candidate standards will be presented to the developing organization for review. They will ensure that the appropriate parties within their context have been informed of the proposed standard and been given an opportunity to review it. The review and comment period may take some time, as it may need to accommodate the workgroup schedules within each context. During this period, the group responsible for proposing the standard should address any comments received. As a result of this review, modification or clarification of the CDEs may be required.

Establish Standards

Propose for Standard. At the end of the review and comment period, the developing organization will determine if the candidate standards should be proposed to the caBIG V-CDE Workgroup as a candidate for adoption as a standard for caBIG. The decision to propose a standard will only be conferred if there is a consensus of all concerned parties that a data element or group of elements meets the criteria for quality and completeness, and are suitable for use across caBIG.

caBIG V-CDE Broad Review and Comment Period. The caBIG V-CDE Workgroup will be responsible for distribution of a proposed data standard to a broad audience for review and comment. They will address any comments received, requesting input from the developing organization as needed. The V-CDE Workgroup may return the proposed data standard to the developing organization for modification/clarification, if necessary.

Assignment of Standard Registration Status. At the end of the Review and Comment Period, the V-CDE Workgroup will either approve the proposed data standard for use by caBIG, decide not to approve the data standard and that no further action is required, or return the data standard to the developing group for modification/clarification. If the V-CDE Workgroup does not make a decision on the disposition of a proposed data standard within 60 days of submission, the registration status of the CDEs in the data standard will automatically be set to Standard.

Review Standards

Maintenance. The governance process will operate in an iterative fashion. On an ongoing basis, Contexts will continue to use the caDSR to find data elements to use to support their efforts. Some changes will need to be made to data elements from time to time to respond to changes in science or other standards. A group may identify requirements for change of an existing data element and initiating a change request with the V-CDE Workgroup. The V-CDE Workgroup will review the request and make recommendations whether to modify the current CDE, continue the current CDE with no change, create a new CDE, or to retire the current CDE. The recommendations will be presented for broad review and comment before consideration for adoption as a new or modified data standard. A modified CDE may be returned to the originating group for review and comment if deemed necessary after the broad review and comment period.

V-CDE Workgroup